

Pyridostigmine Bromide (PB) 30 mg

Please remove and discard previous information provided in the PB packet and replace it with this information sheet.

This Information Sheet also updates the information on the cardboard sleeve and foil pack containing your PB.

The US Food and Drug Administration (FDA) has approved 30 mg PB tablets as a pretreatment against a Soman nerve gas attack.

Therefore, PB is no longer considered investigational when used as a nerve agent pretreatment against Soman.

Discard your PB tablets 3 months after issue.

You must read the following information about PB to find out more about its risks and benefits and how to use it.

Protection Against Chemical Warfare Agents

Pyridostigmine bromide is approved for protection against the chemical nerve agent Soman (GD). Other chemical nerve agents include Sarin (GB), Tabun (GA) and VX. Nerve agents work by making your muscles weak. They can make you lose control of your muscles. You can die if your breathing muscles are paralyzed.

Your main protection against chemical weapons is your chemical protective mask and battle dress overgarment. You also have other items to help you if you are exposed to chemical warfare agents. These items are:

- a. Two antidotes (atropine and 2-PAM) that are part of the MARK I Nerve Agent Antidote Kit or ATNAA (Antidote Treatment – Nerve Agent Autoinjector)
- b. Pyridostigmine Bromide (PB) — PB is approved as a pretreatment against a Soman nerve agent attack. The approval is based on safety studies in humans and effectiveness (how well it works) studies conducted in animals. The FDA has approved PB based only on animal studies of effectiveness because it is not ethical to do these studies in humans. Human studies would require exposing people to the deadly effects of nerve agents, risking poisoning them or even killing them. Studies in monkeys and guinea pigs show that pretreatment with PB makes the antidotes (atropine and 2-PAM) work better against Soman (GD). PB pretreatment in animals has not been shown to make the antidotes (atropine and 2-PAM) work better against other nerve agents. Based on the animal studies of whether PB works against Soman, it is thought that any potential benefits from use of PB occur only if:
 - (1) PB is taken within 8 hours before, but not right before, exposure to the nerve agent Soman. (If PB is taken right before (when the nerve gas attack alarm is given) or during nerve agent exposure, it may not work and may make the effects of Soman worse.)
 - (2) Atropine and 2-PAM are used when symptoms of nerve agent poisoning occur.

How To Take Your PB

1. Your chain of command will tell you when it is time to take PB. This decision will be based on the threat of exposure to Soman nerve agents.
2. You must take 1 tablet of PB every 8 hours until your chain of command tells you to stop taking PB.
3. Do not take PB more often than you are told. **Do not double up on your dose if you miss taking it.**
4. There is no known advantage to taking extra PB right before Soman exposure.
5. No further PB should be taken after nerve agent exposure has occurred, instead:
6. If you experience most or all of the **MILD** symptoms of nerve agent poisoning, you should **IMMEDIATELY** hold your breath (**DO NOT INHALE**) AND PUT ON YOUR PROTECTIVE MASK. Then administer atropine and 2-PAM (*one* MARK I kit or *one* ATNAA).
7. Contact your unit medical officer if side effects from PB continue and limit duty performance.

Who should not take PB

Do not take PB if you:

- have a history of bowel or bladder blockage (obstruction)
- are overly sensitive to anticholinesterase medicines (certain drugs used during surgery like physostigmine, edrophonium, neostigmine, and ambenonium)

Tell your doctor or medic before taking PB if you:

- are pregnant
- have asthma
- are allergic to bromide
- take blood pressure medicine
- have high eye pressure (glaucoma)

Also, tell your doctor about all your other medical conditions you may have including heart problems, or reflux esophagitis (GERD).

Side Effects

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|-----------------------|------------------------------------------------|
| • stomach cramps | • watery eyes |
| • gas | • blurred vision |
| • diarrhea | • runny nose |
| • nausea | • difficulty or tightness in breathing |
| • frequent urination | • acid stomach (including heartburn or reflux) |
| • increase salivation | • tingling of fingers, toes, arms, and legs |
| • sweating | • muscle twitching or weakness |
| • headaches | • muscle cramps |
| • dizziness | |

Most side effects are mild and will go away without treatment. If your side effects do not go away, see your unit doctor or medic.

This is not a complete list of symptoms that may occur. See your unit doctor right away if your side effects are very bad or for any symptoms that concern you.

PB has been safely used and has been FDA approved for over 40 years in the U.S. to treat a disease called myasthenia gravis (MG). Human studies of PB at doses intended for military use have found PB to be generally safe.

About your rights and welfare: DOD may collect information on the use of PB to help decide how best to protect deployed forces in the future. Information that identifies you will remain private (confidential). However, the FDA may review any data collected by DOD for the purpose of evaluating PB. Direct questions about your rights and welfare to your unit medical officer, or e-mail questions to hsrrb@det.amedd.army.mil.

For more information about PB: Talk to your unit medical officer or medic. You can also e-mail questions about PB directly to the U.S. Army Medical Research and Materiel Command at address hsrrb@det.amedd.army.mil.

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